TO: NIH Intramural Scientists

FROM: NIH Deputy Director for Intramural Research

SUBJECT: Implementation of *Guide to Preventing Conflicts of Interest in Human*

Subjects Research at NIH

Attached is the policy entitled *Guide to Preventing Conflicts of Interest in Human Subjects Research at NIH*. This document has been reviewed extensively and was approved by the NIH Deputy Director on January 4. Under the *Guide*, the principal investigators on clinical protocols have new responsibilities.

Please read the *Guide* carefully. Effective immediately:

- 1. Each Principal Investigator (PI) must distribute a copy of this policy to all persons named on the cover sheet of each clinical protocol.
- 2. If any investigators on the protocol have issues related to possible conflicts of interest, these should be discussed and resolved with the IC Deputy Ethics Counselor. If necessary, consultation with the central NIH Ethics Office should occur.
- 3. By **February 1, 2005**, each PI should send a written statement to his/her Clinical Director (CD) indicating that they have distributed the document to all investigators on each protocol for which they are responsible and that no one reported any issues related to conflict of interest, or, if any issues were reported, they were resolved, with a description of the resolution. The CD will pass this information on to the appropriate IRB.
- 4. For new protocols, the same procedure should be followed with the note from the PI about compliance with this guide accompanying the submission of the protocol.

/s/

Michael M. Gottesman, M.D.

cc: Director, NIH
IC Directors
Scientific and Clinical Directors
OD Staff